REMARKS

The Office Action of December 29, 2005 has been carefully considered. Claims 1, 2, 5 and 26 are amended. The amendments to the claims do not add new matter. Claims 20-25 and 30-38 are canceled. Claims 1-19 and 26-29 are pending.

35 U.S.C. § 101

Claims 1-19 and 26-29 were rejected under 35 U.S.C. § 101 as being directed toward non-statutory subject matter. Specifically, the Office Action indicates that the composition as claimed is nothing more than Shilajit itself. Claim 1 and 26 are amended to recite that the composition is of isolated DCPs. The recitation of isolated DCPs distinguishes the claimed composition from the natural product Shilajit. As disclosed throughout the Specification, and in particular on page 20, lines 7-22, isolated DCPs were obtained from Shilajit through a five-step process. The claimed composition of isolated DCPs is substantially different from Shilajit in its natural form and does not exist in nature. Therefore the claimed subject matter is statutory subject matter.

35 U.S.C. § 112 – Written Description

Claims 1-19 and 26-29 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Applicant traverses the rejection.

There is a strong presumption that an adequate written description of the claimed invention is present when an application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). Given the *strong* presumption of the adequacy of the written description for original claims, Applicants assert that the Patent Office has failed to meet its initial burden.

Below, Applicant summarizes the Examiner's arguments in support of the rejection and discusses why they fail to meet the burden put on the Patent Office:

A. "Claims 1-12 and 26-29 are a broad generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any structure class comprising dibenzo-alpha-pyrone." (O.A. page 6)

The written description requirement does not have any disqualification of a claim merely because the genus is broad. The written description requirement for a claimed genus is satisfied through a showing that the inventor had possession of the claimed genus. Possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that the applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics or by a combination of such identifying characteristics, so long as a person skilled in the art would recognize that the inventor was in possession of the claimed genus. MPEP 2163.

The instant specification uses reduction to practice, structural formulas, and a combination of identifying characteristics to show possession of the claimed genus. The specification shows a reduction to practice of a composition of isolated dibenzo-alpha-pyrone chromoproteins (DCPs) described, as to methodology, e.g., in Example 1 (page 21). This reduction to practice is described in further detail, e.g., in Example 4 (pages 22-23), therein confirming the constituent dibenzo-alpha-pyrones and chromoproteins. In Example 4, two species of the genus are described, DCP-I and DCP-II, both demonstrating HPLC and spectroscopic identifying data characteristic of DBP-carotenoproteins. This reduction to practice is still further described in Example 5 (pages 23-24) in which additional species are demonstrated, i.e., a species having low molecular weight lipoprotein and a species having higher molecular weight lipoprotein.

In addition to the reduction to practice, the specification provides description of the DCPs containing dibenzo-alpha-pyrones or their derivatives; phosphocreatine; chromo-peptides of molecular weights of about $\leq$ 2 KD; chromoproteins having MW of about 2 KD to about 20 KD; and lipids having fatty acyl esters of glycerol (pages 2 through 4). In addition, the formula shown on page 2 gives a detailed description of the structure of the dibenzo-alpha pyrones and

the formula on pages 5-6 gives a detailed description of the structure of various species of a dibenzo-alpha-pyrone chromoprotein in support of independent claims 1 and 26.

In representation of the genus, various species are described: (1) the phosphocreatine is described as attached to either the 3- or 8- position of the DBP via an ester linkage; (2) a structural drawing/formula of several species of dibenzo-alpha-pyrones is provided at page 2, lines 12-19, (the various species represented by the choice of R groups; and (3) a structural drawing/formula of a DCP chromoprotein is provided at page 5, line 13 through page 6, line 7 (the various species represented by the choice of R groups).

Thus, consistent with the precepts of MPEP 2163, stated above, representative species of the claimed genus are disclosed in the specification, in satisfaction of the written description requirement.

B. "The claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification." (O.A. page 6)

The guideline regarding disclosure of a correlation between function and structure relates to claims that describe something only in terms of its function (i.e., claiming a gene that expresses a peptide), so that the recited function must have a known correlation to a definite structure. Where, as here, the thing is not claimed in terms of its function, the disclosure of a correlation between function and structure does not apply. The instant claims recite definite structural elements, e.g., dibenzo-alpha-pyrones, phosphocreatine, chromopeptides of MW $\leq$ 2 KD; and lipids having fatty acyl esters of glycerol. One of skill in the art knows what these structural elements are.

Where, as here, the applicant shows a reduction to practice, drawings, or disclosure of relevant, identifying characteristics, these alone suffice to satisfy the written description requirement. MPEP 2163, supra.

C. "There is not a specific example of a compound comprising a dibenzo-alpha-pyrone that discloses specific chromo-proteins, lipids, and the various functional groups claimed for the dibenzo-alpha-pyrone moiety." (O.A. page 7)

The Examiner's concern about lack of a specific example is of no moment toward the satisfaction of the written description requirement. MPEP 2163 makes it clear that description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. MPEP 2163.

In like manner, the formula shown on pages 5 and 6 of the specification provides a clear depiction to support a claim for a composition of isolated dibenzo-alpha-pyrone chromoproteins as claimed in independent claims 1 and 26. The formula **does** provide various functional groups for the dibenzo-alpha-pyrone moiety and **does** provide for various species of lipids having fatty acyl esters of glycerol, from which specific examples can be chosen. Disclosure of specific chromoproteins is found in the reduction to practice description of Example 4 (page 22), wherein two chromoproteins are described by a combination of identifying characteristics.

D. "While having written description for dibenzo-alpha-pyrone identified in the specification tables and/or examples, the specification is void of specific peptides, organic molecules (lipids and chromo-peptides) that qualify for the functional characteristics claimed as the biomolecules." (O.A. page 7)

The claims are directed to a composition of isolated DCPs that are claimed by means of definite constituents, not by functional characteristics. The Examiner has conceded that there is sufficient written description of the dibenzo-alpha-pyrones. The other constituents of the DCPs of the independent claims include phosphocreatine; chromo-peptides of molecular weights of about $\leq$ 2 KD; and lipids having fatty acyl esters of glycerol. These are not constituents described in terms of their functional characteristics. These are descriptions of definite biological substances that one of skill in the art would recognize, and as noted directly above in part C, the specification provides formulas, description and reduction to practice of these

constituents. Thus the written description requirement is satisfied.

E. "The claimed and disclosed molecular structure is merely a potential structure based on chemical and not structural determination." (O.A. page 7)

Patentability of a product cannot be denied on the basis of the method of making it. It doesn't matter whether the claimed molecular structure was conceived as a result of chemical or structural analysis. Furthermore, the claimed and disclosed molecular structure is not a "potential structure," it is definite. It is presented as a structural formula with definite options for the constituents. So long as one skilled in the art would understand what that structure is, the written description requirement is satisfied, as here.

F. "There is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed." (O.A. page 7)

This argument is of no moment to the satisfaction of the written description requirement. This argument relates to the analysis of enablement not written description.

Applicant has rebutted the Examiner's grounds for the rejection. In light of having disqualified all the grounds, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

35 U.S.C. § 112 – Enablement

Claims 1-19 and 26-29 are rejected under 35 U.S.C. § 112, first paragraph, because the Examiner alleges the specification, while being enabling for a composition of a fractionated extract of Shilajit, does not reasonably provide enablement for the specific compositions claimed. Applicant traverses the rejection.

The Examiner argues that "since the defined core structure that is correlated with the pharmaceutical function remains largely unsolved, means for determining both is highly unpredictable. The specification has provided an alleged structure, or best guess, of a generic."

Applicant disagrees. The specification provides a structural formula for the claimed invention at pages 5 and 6 that provides the necessary guidance for one skilled in the art to understand what the claimed composition is. The specification also provides instructions in examples 1-3 (pp. 21-22) on how to isolate the claimed composition from a variety of sources

including Shilajit, marine invertebrate fossils and living marine invertebrates. Further, the specification describes, by experiment, how the claimed composition is useful for relieving symptoms due to chronic stress (Example 9, pp. 24-30). Thus, contrary to the Examiner's argument, clear guidance is provided, by example, to obtain the claimed composition, clear formulas are provided to recognize the claimed composition, and clear guidance by example is provided to test that the claimed composition is useful. The Examiner's allegation that one skilled in the art would be burdened with undue experimentation is refuted by the examples in the specification. In light of having disqualified the Examiner's grounds for the rejection, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

35 U.S.C. § 102

Claims 1-19 and 26-29 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,405,613 to Rowland. Rowland discloses compositions of Shilajit or aqueous Shilajit extracts in combination with vitamins as a pharmaceutical or nutritional supplement. The Examiner asserts that, given the use of Shilajit directly, and not the extract, the composition as a pharmaceutical and/or nutritional supplement would contain all of the compounds instantly claimed in natural product claims 1-12 and 26-29.

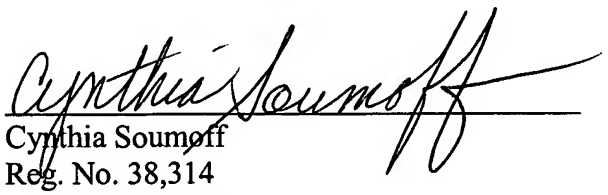
Amended claims 1 and 26 recite a composition of "isolated" dibenzo-alpha-pyrone chromoproteins (DCPs). Thus, the claims are not directed to natural Shilajit. Rowland does not teach that Shilajit contains dibenzo-alpha-pyrones, notwithstanding that Rowland lists the composition of Shilajit in Table 7. Further, Rowland's extract of shilajit is merely a water extract, while the instant application provides for a five-step process for isolating a composition of isolated dibenzo-alpha-pyrones. Rowland does not disclose an isolated composition of dibenzo-alpha-pyrone chromoproteins, as in the claimed invention. For this reason Applicant requests that the rejection be reconsidered and withdrawn.

In view of the foregoing, Applicant submits that all pending claims are in condition for allowance and requests that all claims be allowed. A prompt action on the merits is earnestly solicited. The Examiner is invited to telephone the undersigned should he believe this would

expedite prosecution of this application. It is believed no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

Dated: June 2, 2006



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